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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,777	11/26/2003	Bruce Kevin Wagoner	4237-101	9677
23448	7590	07/31/2006	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329 RESEARCH TRIANGLE PARK, NC 27709			LEITH, PATRICIA A	
		ART UNIT	PAPER NUMBER	1655

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,777	WAGONER, BRUCE KEVIN	
	Examiner	Art Unit	
	Patricia Leith	1655	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 5/5/06.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Claims 1-42 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Applicant's arguments are moot in light of the following new rejections:

Claim Rejections - 35 USC § 102

Claims 1, 2, 7, 8, 10, 32 and 35-37 are rejected under 35 U.S.C. 102(b) as being, anticipated by Brasher (2001).

Brasher (2001) reporting for the Times Union indicated that a hunter-friendly soap was being sold on the market which only contained lye, distilled water, olive oil, coconut oil, palm oil, aloe vera, shea butter and glycerin (see the Abstract as well as page 2. It is noted that the olive, coconut and palm oil can act as emulsifiers. Also, washing the skin is a means of treating or debriding or softening the skin (with regard to claims 35-37).

Claims 1-3, 7-8, 10, 32 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Krzysik (US 6,440,437 B1).

Krzysik (US 6,440,437 B1) specifically claimed a composition comprising glycerin, soy sterols, sunflower oil and excipients such as petrolatum, glyceryl stearate and oils such as mineral oil and camellia oil for example for example (thickeners/emulsifiers) (see all claims, specifically claims 19, 23, 30,32 and 36). Krzysik taught that this composition could be used for lightening the skin, and because of the oils and glycerin contained in the composition, it would have inherently softened the skin upon topical contact.

Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (US 6,121,317 A).

Wu et al. (US 6,121,317 A) specifically claim a topical composition comprising urea and cocoa butter (see claims 20 and 21). Applicant may argue that these components are present in Markush Groups rendering the claims only obvious over Wu et al. However, because the components were listed in the claims, every possible embodiment is claimed. Markush format of claims still provides the patent with the protection for the combination of embodiments, however, allows Applicant to condense the phraseology of the claims and thus lessens the burden of having to submit claims to every combination of invented embodiment.

Claim Rejections - 35 USC § 103

Claims 1-3, 5, 7-10 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huard et al. (US 6,485,733 B1) in view of Nagel (1977).

To reiterate from the previous Office Action, Huard et al. (US 6,485,733 B1) disclosed that the ingredients of Vaseline™ Intensive Care Extra Strength Lotion included, *inter alia*, sunflower seed oil, soya sterol, glyceryl stearate, stearic acid, triethanolamine, glycerine, water, lecithin, tocopherol acetate, retinyl palmitate, disodium EDTA and urea (see col. 18, lines 51-63).

It is noted that *Helianthus annuus* is the botanical name for sunflower.

Huard et al. did not discuss the omission of parabens from Vaseline™ Intensive Care Extra Strength Lotion.

It is well known in the art that people suffer from paraben allergies. Nagel et al. (1977) for example, reported paraben allergies to be on the rise, indicating that about 3% of the population had a topical paraben allergy (see p. 1594, column 1). Nagel et al.

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urged the indiscriminate use of parabens as preservatives "especially not in medicines frequently given to the allergic or potentially allergic patient" (see p. 1595, column 3).

One of ordinary skill in the art would have been motivated to formulate Vaseline™ Intensive Care Extra Strength Lotion without parabens in order to manufacture a topical moisturizing product which was safe for persons allergic to paraben preservatives. It was clear from the prior art that a percentage of the population was allergic to topically-applied compositions comprising parabens. Therefore, the ordinary artisan would have been motivated to create paraben-free forms of known topical compositions in order to meet the demands of the public.

Claims 1- 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huard et al. (US 6,485,733 B1) in view of Nagel (1977) in view of Quan et al. (US 6,180,133 B1) in view of Durr et al. (US 5,997,889) in view of Hill et al. (US 4,233,295) and in view of McNulty et al. (US 2005/0048105 A1).

The teachings of Huard et al. and Nagel et al. were discussed *supra*. Neither reference taught the incorporation of shea butter, ammonium lactate, butylated hydroxytoluene or sodium polyacrylate into the Vaseline™ composition, nor did they discuss a composition consisting essentially of or comprising agents such as glycerin and shea butter.

Quan et al. (US 6,180,133 B1) teaches that studies indicated that addition of ammonium lactate to lotions had proven moisturizing activity (col. 3, line 64- col.4, line 17).

Durr et al. (US 5,997,889) disclosed that shea butter may be added to a lotion to improve its moisturizing ability (see Abstract for example).

Hill et al. (US 4,233,295) teaches that butylated hydroxytoluene, an antioxidant, is advantageous to incorporate into creams, lotions or ointments in order to preserve the active ingredients therein (see col. 6, lines 23-26).

McNulty et al. (US 2005/0048105 A1) teaches that sodium polyacrylate is a known thickening agent for creams and lotions[0069].

One of ordinary skill in the art would have been motivated to combine ammonium lactate and shea butter into the Vaseline™ composition because they are ingredients well known to improve moisture to the skin. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for lending moisture protection to the skin. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the

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ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been motivated to incorporate butylated hydroxytoluene to the Vaseline™ composition in order to preserve the active ingredients therein. It was clear from the prior art that butylated hydroxytoluene was used as an antioxidant in creams and lotions. Thus, the ordinary artisan would have had a reasonable expectation that the addition of this ingredient would have afforded the Vaseline™ lotion a longer shelf-life. Further, the substitution of butylated hydroxytoluene for methylparaben would have been advantageous in the formulation of a product which was free from paraben-allergen containing ingredients.

One of ordinary skill in the art would have been motivated to add sodium polyacrylate to the Vaseline™ composition, or alternatively, to substitute sodium polyacrylate for another thickener in Vaseline™ such as glycerine because the addition of thickening agents to lotions imparts a thicker viscosity to the lotion which has a pleasant consistency and further is easy to administer to the skin and these thickening agents are considered functional equivalents as they perform the same function; thickening the lotion.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the cosmetic and pharmaceutical arts. One of ordinary skill in the art would have been motivated to have modified the proportions of ingredients in the lotion in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment (e.g., regular strength –vs- extra strength). Such variations in amounts of cosmetically/ pharmaceutically active ingredients is considered merely optimization of result effective variables, conventional practice in the art of pharmacology.

It is clear from the prior art cited herein that shea butter and ammonium lactate were both well known skin moisturizing ingredients (see Quan et al. and Durr et al.). Therefore, one of ordinary skill in the art would have been motivated to combine these ingredients either alone (consisting of) or with inert carriers (consisting essentially of) or combined with other moisturizing ingredients (comprising) because, again, mixing two (or more) components which are useful for the same purpose is considered obvious. One of ordinary skill in the art would have had a reasonable expectation that the combination of shea butter and ammonium lactate (for example) either alone, or with

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inert carriers or with other active moisturizing ingredients would have provided for moisturizing effects when administered topically because each ingredient is known to be used in skin care ingredients.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

July 17, 2006

A handwritten signature in black ink that reads "Patricia Leith". The signature is fluid and cursive, with "Patricia" on top and "Leith" below it, though the two names are connected by a single stroke.